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Telephone No.: Re: U.S. Patent Application No. 09/654,227 Wolfgang HEIL Our Ref. PLOVIN-1A		
Total No. of Pages: 37 if you do not receive all pages, please call (703) 243-6333		

I hereby certify that the attached

- 1) Reply to Office Action mailed March 23, 2004 (4 pages)
- 2) Amendment Related to Inventorship Issues (23 pages)
- and
- 3) Request for Correction of Inventorship (9 pages)

are being facsimile transmitted to the Commissioner of Patents,  
Box 1450, Arlington, Virginia 22313-1450, on March 29, 2004.

Sincerely,

*Jennifer J. Branigan*  
Jennifer J. Branigan  
March 29, 2004

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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MAR 29 2004

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In re Application of:

Wolfgang HEIL et al

Confirmation No.: 5622

Serial No 09/654,227

Examiner: S. Hui

Filed: August 31, 2000

Group Art Unit: 1617

For: PHARMACEUTICAL COMPOSITION FOR USE AS A CONTRACEPTIVE

**REPLY**

**Mail Stop Non-Fee Amendment**

Commissioner for Patents

P.O. Box 1450

Alexandria VA 22313-1450

Sir,

This Reply is responsive to the Office Action mailed March 23, 2004. See also the "Amendment Related to Inventorship Issues and Formal Matters" filed concurrently.

**The Rejection under 35 U.S.C. §103**

The rejection of claims 1, 3-7, 9-14, 16-19, 21-22 and 36-69 under 35 U.S.C. §103, as being obvious over Gast (WO 98/04269) and Elliesen (U.S. Patent No. 5,922,349) in view of DeCastro (U.S. Patent No. 5,534,270), is respectfully traversed

It is alleged in the Office Action that, from DeCastro, it would have been obvious to modify the Gast and Elliesen compositions by micronizing drospirenone.

In fact, DeCastro teaches that "[m]any factors can affect bioavailability including ... e.g., dissolution rate of the drug" and that "the rate of dissolution of a particulate drug can increase

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with increasing surface area, i.e., decreasing particle size" (emphasis added). See, e.g., col. 1, lines 14-16 and 27-29. Thus, at most, DeCastro teaches that decreasing particle size might, in general, be helpful in increasing dissolution rate and/or bioavailability of a drug, including the generally mentioned "steroids" among many other classes of compounds.

Applicants have previously submitted evidence establishing, with respect to other disclosures along the lines of DeCastro, the lack of motivation to micronize drospirenone for any reason, including to increase the rate of dissolution and/or to increase bioavailability. The Supplemental Amendment and Reply filed March 10, 2003, included a Declaration by Dr. Lipp. It provided expert opinion with supporting documentary evidence that, based on the known properties of drospirenone, one of ordinary skill in the art would not have been motivated to micronize it or provide it in a form promoting its rapid dissolution. In fact, one would have been directed away from providing it in a form promoting rapid dissolution in view of its known isomerization to an inactive form under acidic conditions (such as in the stomach upon oral administration).

#### The Rejection under 35 U.S.C. §112, first paragraph

The rejection under 35 U.S.C. §112, first paragraph, is rendered moot by the amendment of claims 7, 45, 47, 49 and 58 to correct an obvious typographical error. See the "Amendment Related to Inventorship Issues and Formal Matters" and the proper recitation of the  $\pm 0.5^{\circ}\text{C}$  language in the claims, as supported by the disclosure in Example 2, page 12, line 11, of the specification, for example.

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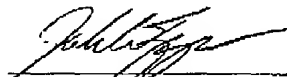
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**The Provisional Obviousness-type Double Patenting Rejection**

The provisional obviousness-type double patenting rejection over copending application Ser. No. 10/359,085 is rendered moot by the terminal disclaimer filed herewith. The terminal disclaimer is also directed to related copending application Ser. Nos. 10/359,062; 10/359,069, and 10/359,082 to eliminate any potential (though not admitted) obviousness-type double patenting issues with these applications.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted.



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Date: March 29, 2004

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